

Figure 2

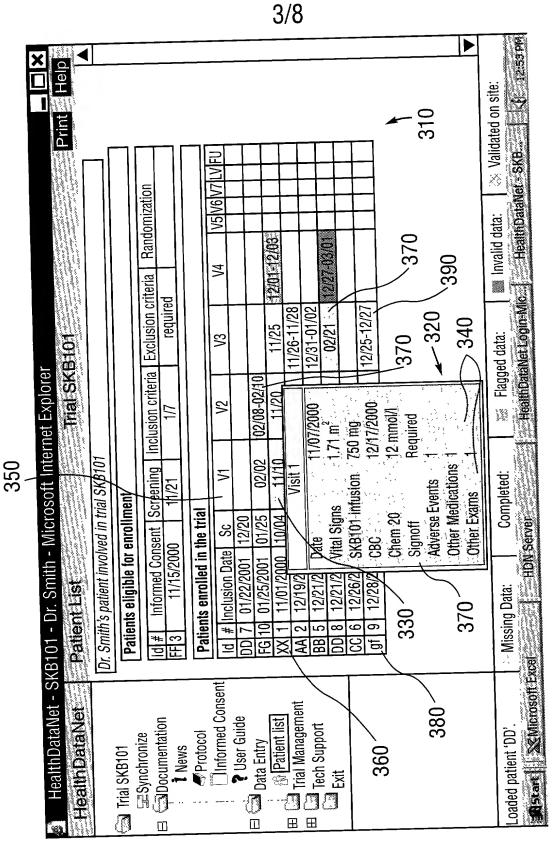


Figure 3

200

| | Back to list Age: 45 End: | Last Visit +[6-8] | | | | | | Brief | before | before | 440 mg/m ² | after infusuion | fter infusuion | fter infusuion | required | | to check | to check | to check | -410 |
|-----|---|---|--------------------|----------------------------------|------------------|----------------|---------------------------------------|---------------|-----------------------|---------|---|---|--|---|-----------|---|-------------------|-------------------|-----------------|------|
| | Print Help Age | Visit7+[6-8] | | | | | | Brief | before | | 440 mg/m ² | after infusion after infusion after infusion after infusion after infusion after infusion after infusuion a | after infusion after infusion after infusion after infusion after infusion after infusionafter infusuion after infusuion | after infusion after infusion after infusion after infusion after infusuion after infusuion | required | - | to check | to check | to check | |
| | Print Sex: Female hclusion: 42/28/2000 | Visit6 +[6-8] | | | | | | Brief | before | | 440 mg/m ² | after infusion | after infusion | after infusion | required | - | to check | to check | to check | |
| // | Melusion | Visit5 +[6-8] | | | | | | Brief | before | | 440 mg/m ² | after infusion | after infusion | after infusion | required | | to check | to check | to check | |
| 430 | ded //2000 | Visit4 +[6-8] | | | | | | Brief | before | before | 440 mg/m ² | after infusion | after infusion | after infusion | required | | to check | to check | to check | |
| \ | Status: Included Consent: 12/06/2000 | Visit3 / 12/25-12/27 | | | | | | Brief | before | | 440 mg/m ² 440 mg/m ² | after infusion | after infusion | after infusion | required | | to check | to check | to check | |
| | | Visit2 / | | | | | | 01/24/2001 | before | | 440 mg/m ² | after infusion | after infusion | | required | | to check | 1 | to check | 450 |
| 50 | Trial SKB101 Number: 9 Unit #: 122 | Visit1 / | | | | | | | 1.66 m ² < | | 700 mg | after infusion | after infusion | | required | | to check | _ | to check | 4 |
| 42 | 63 | Screening 12/05/2000 | S S | #556363 | 4 cm | Negative | 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 | 12/28/2000 | 1.74 m ² | 65 U/ml | | 01/25/2007 | 149-mmol/I | Į. | /required | | | - | to check | |
| | Patient gf(# 9) Initials: gf Random #: 556363 | Date | Exclusion criteria | Randomization Medical History | Tumor Assessment | Pregnancy test | 606 | Physical Exam | Vital Signs / BSA | CA-125 | SKB101 infusion | CBC | Chem 20 | Toxicity Assessment | Signoff | | Adverse events // | Other Medications | Other Exams / / | 440 |

igure 4

| Print - Help - Back to list | Age: 45 End: | Last Visit after infusuion | | | | | Brief | before | betore | 440 mg/m² | | | required | to check | to check | to check | 510 | | |
|--|--|--|--------------------|---------------|--------------------|----------------|------------|----------------------------------|---------------------|--|---|---|--------------------------------|----------|----------------|-------------------|---------------------|----------|------------|
| aleH w | Age | Visit4 Visit5 Visit6 Visit7 after infusion after infusion after infusion a | | | | | Brief | before | | 440 mg/m² | after infusion after infusion after infusion after infusionalter infusion | after infusion after infusion after infusion after infusionalter infusion | required | to check | to check | to check | | | |
| Print | Sex: Female Inclusion: 12/28/2000 | Visit6 after infusiona | | | | | Brief | before | | 440 mg/m ² | after infusion | after infusion | required | to check | to check | to check | | | |
| en e | Sex: Inclusion | Visit5 | | | | | Brief | before | | 440 mg/m ² | after infusion | after infusion | required | to check | to check | to check | 0 | Ŋ | • |
| ergen i Serie de Ser Serie de Serie de | led 2000 | Visit4 Ifter infusion a | | | | | Brief | before | before | 440 mg/m ² | after infusion | after infusion | required | to chack | tycheck | to check | 550 | Figure 5 | |
| en e | Status: Included Consent: 12/06/2000 | Visit3 12/25-12/27 | | | | | Brief | hefore | | 440 mg/m ² | after infusion | affer Infusion | reduired | Apolo of | to check | to check | ← 530 | | |
| e de Porto de Constante de Cons | | Visit2 12/19/2000 | | | | | 01/24/2001 | hefore | | 12/01/2000 | 65 in 39 | 14516 | SEC. | | Regular | | 135 mmHg 56 mmHg | 7 025 | |
| 09 | Frial SKBTUT Number: 9 Unit #: 122 | Visit1 | | | | | | 1 58 m2 | Vital Signs | SI S | 9 | | | | | | | | - |
| 5(| | Screening 19/05/2000 | OK OK | #556363 | 12/28/2000 4 cm | Negative | 1 | 12/28/2000 1 7 m ² | -114/11 | Date | 10 He/ont | - | | | | ¥ | ₹ | | 5 0 |
| is an experience of the second | Patient gf(# 9)* Initials: gf Random #: 556363 | **** | Inclusion criteria | Randomization | Medical History | Pregnancy test | 606 | Physical Exam | Vital Signs / BSA / | SKR101 inflision | CBC | Chem 20 | Toxicity Assessment Signoff | | Adverse events | Other Medications | 570 | 520 | |

<u> 19975649 191491</u>

6/8

| alidation status of collec | eted forms | | |
|----------------------------|----------------|----------------------------------|--------------------------------------|
| Not/ Available Data | | 620===== | |
| Confirmed Data | | Form | Visit |
| Initials | <u>Patient</u> | Form Date: 10/04/2000 | Screening |
| XX\ | 1 | Date: 11/15/2000 | Visit 1 |
| AA | 2 | | Visit 1 |
| gf | 9 | SKB101 infusion: 700 mg | Visit 1 |
| DD | 8 | SKB101 infusion: 800 mg | Screening |
| XX | 1 | Signoff: 11/09/2000 | Outdoming |
| ₆₃₀ | B `630A | | |
| Flagged Data | | Form | Visit |
| Initials | Patient | Form | Screening |
| FF | 3 | CA-125: 14 U/ml | Screening |
| FF | 3 | Inclusion criteria: 1/7 | Visit 1 |
| AA | 22 | SKB101 infusion: 710 mg | Visit 1 |
| XX | 11 | Vital Signs: 1.71 m ² | Visit 2 |
| XX | 11 | Vital Signs: 11/27/2000 | /630 |
| | 30C | | <u>/ชงบ</u> |
| Validated Data | | F | Visit |
| Initials | Patient | Form | Screening |
| XX | 11 | Chem 20: 15mmol/ | Screening |
| XX | 11 | Exclusion criteria: ok | Screening |
| XX | | GOG: 1 | All Visits |
| XX | 1 | history: 11/20/2000 | Screening |
| XX | 11 | history: 11/21/2000 | Screening |
| XX | 1 | Tumor Assessment: 13 cm | Visit 1 |
| fg | 10 | Vital Signs: 1.85 m ² | 650 |
| 670 | 630D | Forms | 030 |
| Invalid Data | | Date 02/02/2001 | Visit |
| Initials | Patient | Height, 170 cm | Screening |
| BB | 5 | Weight 160 lb | Visit 3 |
| DD | 8 | Temperature 99 F | Visit 1 |
| DD | 8 | Temperature site Oral | Screening |
| DD | 8 | Pulse 65 | Visit 3 |
| DD | 8 | Pulse type Regular | Screening |
| FG | 10 | Repiration 45 | |
| | | Stop 135 mmHg | 0.40 |
| | 660 | Dbp 70 mmHg | < 640 ⁶ 610 |

Figure 6

| in state |
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| Back to Age: 45 End: | Last Visit +[6-8] | | Brief | before | 440 mg/m ² | _ | | required | to check | to check | to check | 740 | 2 |
|---|--|---|-------------|---------|-----------------------|-----------------|---|---|-----------|----------------|-------------------|-----|----------|
| Print Help Back to list Rale Age: 45 A | Visit7 +[6-8] | | Brief | before | 440 ma/m ² | after infusuion | / daysbefore after infusion | after infusion after | to check | to check | to check | | |
| -720 Print Sex: Female Inclusion: 12/28/2000 | Visit6 +[6-8] | | Brief | before | 440 ma/m² | after infusion | after infusion | after infusion required | to chack | to check | to check | | |
| 720 Sex: Inclusion | Visit5 +[6-8] | | Brief | before | 440 ma/m² | after infusion | after infusion | after infusion required | Jodo ot | to check | to check | | 7 |
| del Help | (Kimu/an/yy) | | | | | lafter infusion | after infusion | required | 7000 | to check | to check | | Figure 7 |
| | | · | | /mmHgl | MIIIIIIIII | after inflicion | after infusion | after infusior | - | to check | to check | | |
| Internet Explorer | | oral 58 regular | 14 | | XQ / CQ / | offer inflicion | afferinfusion | raniirad | | to check | / to check | ∤ B | |
| | 7 7 Height Click here to validate this value (if conforms to the source documents) | site | | | | | e after influsion | | nadiinhai | | to check | 100 | |
| s - Micros | e ght s validate this to the sourc | Temperature Temperature site Pulse rate | Respiration | BP: SBP | BP. DBP/ | Can | / daysberor | | nallinha | | to check | _ | |
| ္က လ လ | Date 3 Date 3 Height Glick here to valid conforms to the | | · · | | | | CBC | Toxicity Assessment | Signori | Adverse events | Other Medications | 750 | |

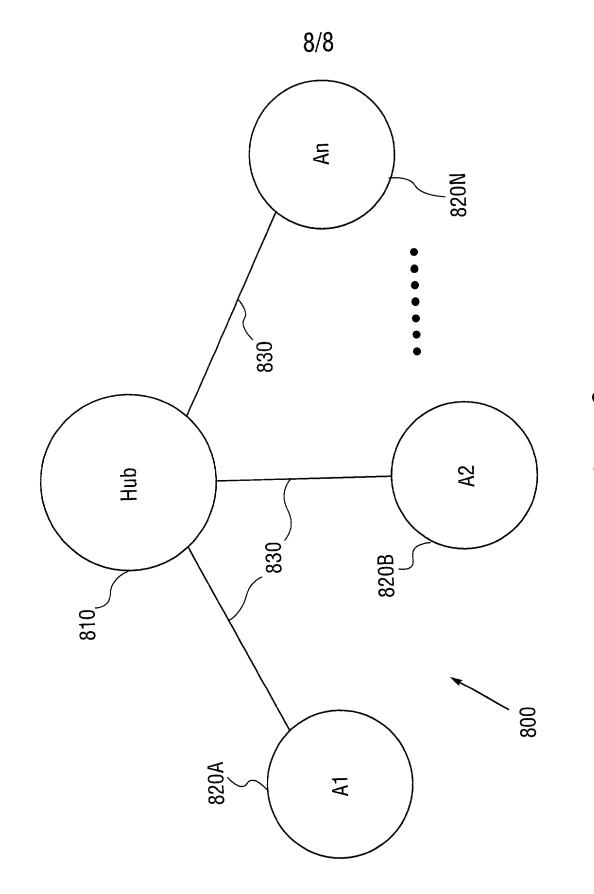


Figure 8